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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,957	02/04/2000	Winston J. Thomas	8907-087-999	8113
20583	7590	12/10/2004		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER

1634

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/497,957

Applicant(s)

THOMAS ET AL.

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 92-94,96-99,101-112 and 124-137 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102-112 is/are rejected.
- 7) ☒ Claim(s) 92-94,96-99,101 and 124-137 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed September 13, 2004. Currently, claims 92-94, 96-99, 101-112, 124-137 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 13, 2004 has been entered.

2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

3. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims and applicant's arguments.

Election/Restrictions

4. Applicant's election of SEQ ID NO: 1 has been received. Upon review of the instant application and prosecution history, it was unclear why a subsequent restriction was required following the non-final office action mailed on July 16, 2001 which examined SEQ ID NO: 3. As discussed with Roger Rich on March 24, 2004, the previous restriction requirements are withdrawn and prosecution will continue with the instant claims as they correspond to the originally elected SEQ ID NO: 3.

5. Therefore, Claims 92-94, 96-99, 101-112, 124-137 as applied to SEQ ID NO: 3 are under examination.

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Priority

6. This application claims priority to several applications. The application 08/632,673, filed April 15, 1996 fails to disclose plasmids or SEQ ID NO: 3. Therefore, the instant application appears to receive the benefit of 08/6552,265, filing date May 23, 1996.

Drawings

7. The drawings are acceptable.

New Matter

8. Claims 136 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amended claims, reference to "a monkey cell" are included. The specification does not describe or discuss "a monkey cell". Instead the specification describes pig, sheep, goat, ape, orangutan, primate. This description does not support monkey. The concept of "a monkey cell" does not appear to be part of the originally filed invention. Therefore, "monkey cell" constitutes new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

The response traverses the rejection. The response asserts the specification on page 49, lines 9-10 teaches useful host cells including VERO cell line. The response states that VERO cell line the source of which is the kidney of the African Green

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Monkey. This argument has been reviewed but is not convincing because the genus encompassed by monkey cell is not described by a single specific species, namely VERO. Since the specification does provide support for VERO, the species of VERO would be supported and not considered new matter. Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 102-112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a plasmid comprising a coding sequence wherein the coding sequence consists of at least 8-18 consecutive nucleotides from SEQ ID NO: 3.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed”. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from

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its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, Applicant has defined only a fragment from a nucleic acid sequence embedded within a larger sequence. The claims broadly encompass SNPs, variants, splice variants, mutations, translocations etc. of the nucleic acid of SEQ ID NO: 3 in addition to homologues of the sequences from different species of animals which have not been described in the instant specification. Further, an 18-mer embedded within a larger sequence also encompasses post-filing date mouse, rat and pig sequences. The post-filing date art also teaches sequences from humans which were not contemplated at the time the invention was made.

Although applicants have amended their claims to require a coding sequence wherein the coding sequence consists of at least 8-18 consecutive nucleotides from the

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particular locations provided, the claim remains drawn to a nucleic acid of at least 18 nucleotides embedded within a larger sequence since the claim is drawn to comprising. The claim would encompass 8 nucleotides attached to additional sequences. The claims are not drawn to be limited to a plasmid consisting of a coding sequence wherein the coding sequence consists of at least 8 consecutive nucleotides and a heterologous sequence. Applicant is reminded that no new matter may be added to the claims.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Response to Arguments

The response traverses the rejection. The response asserts the rejection is overcome in view of the amendments to the claims 102-112. This argument has been reviewed but is not convincing because the claim would encompass 8 nucleotides attached to additional sequences. The claims are not drawn to be limited to a plasmid consisting of a coding sequence wherein the coding sequence consists of at least 8 consecutive nucleotides and a heterologous sequence.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Interpretation

10. It is noted that Claims 124-137 are drawn to a cell comprising the expression plasmid which is an expression vector. The claims are directed to mammalian cells including primate, monkey and human cells. Upon review of the instant specification, it

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has been determined that the claims do not read on an intact organism and therefore does not read on a human being.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 102-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (Genbank Accession Number R12707, April 1995).

Hillier et al. (herein referred to as Hillier) teaches a nucleic acid in plasmid pT3T3d (Pharmacia). The nucleic acid plasmid comprises 20 consecutive nucleotides of SEQ ID NO: 3 (limitations of Claim 102-112). Nucleotides 876-895 of SEQ ID NO: 3 are 100% identical to nucleotides 335-316 of Hillier. The plasmid comprises a coding sequence that consists at least 20 consecutive nucleotides from SEQ ID NO: 3. The plasmid comprises the fragment consisting of these 20 nucleotides, as required by the instant claims. Thus, Hillier teaches every limitation of the instant claims.

Conclusion

12. Claims 92-94, 96-99, 101, 124-137 contain allowable subject matter, namely the nucleic acid of SEQ ID NO: 3 and a nucleic acid sequence encoding a polypeptide sequence of SEQ ID NO: 4. The art fails to teach a nucleic acid of SEQ ID NO: 3 or

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encoding a polypeptide of SEQ ID NO: 4 prior to the filing date. SEQ ID NO: 1-2, 5-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected sequences, there being no allowable generic or linking claim. This application contains SEQ ID NO: 1-2, 5-12 drawn to an invention nonelected with traverse in the paper filed April 30, 2001. A complete reply to the final rejection must include cancellation of nonelected subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

13. Claims 102-112 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeanine Goldberg
Patent Examiner
December 8, 2004